FDA's Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals

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Basis of FDA's Authority

- The Federal Food, Drug, and Cosmetic Act
- Title 21 Code of Federal Regulations (CFR)
  Parts 800 to 1299

How FDA Classifies Medical Devices

- Class I, Class I exempt
- Class II, Class II exempt
- Class III

Types of Premarket Submissions

- 510(k) = Substantial Equivalence (SE) to a marketed device
- PMA = a new device not previously marketed or an existing device seeking a new intended use
- Pre-amendment devices = devices marketed before 1976

FDA's Regulatory Requirements for Third Party and Hospital Reprocessors of Single-Use Devices (SUDs)

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- www.fda.gov/cdrh/comp/guidance/1168.pdf

FDA's Enforcement Guidance

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- Registration & Listing (21 CFR Part 807)
- MDR reporting (21 CFR Part 803)
- Medical Device Tracking (21 CFR Part 821)
- Medical Device Corrections & Removals (21 CFR Part 806)
- Quality System Regulation (21 CFR Part 820)
- Labeling requirements (21 CFR Part 801)
- Premarket notification & approval requirements (21 CFR Parts 807 & 814)

1. Registration & Listing

- Owners and operators of establishments who manufacturer devices, including reprocessing of SUDs, must:

- Register their establishment with FDA (FDA form 2891) and
- List each device (FDA form 2892)

2. Medical Device Reporting (MDR)

- Device-related Deaths, Serious Injuries and Malfunctions.
- Report within 30 calendar days after becoming aware of the event.
- Report within 5 workdays after becoming aware when event involves a remedial action.
- Submit baseline reports; annual updates as necessary.

3. Medical Device Tracking

- Purpose: to promptly locate devices in commercial distribution in the event corrective action or notification about the device is necessary

- Triggered by a specific FDA Tracking Order to the manufacturer/reprocessor

4. Medical Device Corrections and Removals

- Must submit within 5 workdays, a written report to FDA of any corrective or removal of a device that pose a public health risk

  - Correction - the repair, modification, adjustment, relabeling, destruction or inspection of a device including patient monitoring …

  - Removal - moving the device to another location for the purpose of repair, modification, adjustment, relabeling, destruction, or inspection ...

5. Quality System Regulation

- Governs the methods used in, and the facilities and controls used for the design, manufacturer, packaging, labeling, storage, installation, and servicing of all finished devices.

- Process Validation!

6. Labeling

- General labeling requirements on the device and on all packaging.
- Not limited to just adequate directions for use.

7. Premarket Submission Requirements

- 510(k)

or

- PMA

Significant Dates for All SUD Reprocessors:

- Feb 14, 2001:
  - Submit 510(k)/PMA for all class III SUDs
- Aug 14, 2001:
  - Submit 510(k) for all non-exempt class II SUDs
- Feb 14, 2002:
  - Submit 510(k) for all non-exempt class I SUDs

Special Provision for Hospital Reprocessors

- One year enforcement discretion for non-premarket requirements:
  - registration & listing
  - MDR
  - tracking
  - corrections & removals
  - quality system

FDA Home Page on Reuse

- www.fda.gov/cdrh/reuse/index.shtml